Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA–2013–N–1529]

Medical Device Classification Procedures; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the **Federal Register** of March 25, 2014. In the proposed rule, FDA requested comments on its proposal to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions in the Food and Drug Administration Safety and Innovation Act (FDASIA), to update its regulations by proposing changes unrelated to the new FDASIA requirements, and to codify the procedures and criteria that apply to classification and reclassification of medical devices and to provide for classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published March 25, 2014 (79 FR 16252). Submit either electronic or written comments by September 22, 2014.

ADDRESSES: You may submit comments, identified by Agency name and Docket No. FDA–2013–N–1529, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–1529 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marjorie Shulman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1536, Silver Spring, MD 20993–0002, 301–796–6572; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 25, 2014 (79 FR 16252), FDA published a proposed rule with a 90-day comment period to request comments on the Agency's regulations governing classification and reclassification of medical devices to conform to the applicable provisions in FDASIA and proposed changes unrelated to the new FDASIA requirements to update its regulations governing classification and reclassification of medical devices. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for governing classification and reclassification of medical devices to conform to the applicable provisions in FDASIA and proposed changes unrelated to the new FDASIA requirements to update its regulations governing classification and reclassification of medical devices.

The Agency has received requests for an extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: June 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13705 Filed 6–11–14; 8:45 am]

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